SIU 7396
PATENT

REMARKS

No claims have been amended herein. After entry of this Letter To The Patent and Trademark Office claims 20-29, 32-41 and 57-74 are pending.

Claim rejections under 35 U.S.C. § 112

Reconsideration is respectfully requested of the rejection of claims 20-29, 32-41 and 57-74 for not satisfying the enablement requirement of 35 U.S.C. § 112, first paragraph for treating noise-induced ototoxicity. The Office states the "results from rescue dosing of animals after they were exposed to noise did not result in significance."[1] Applicant respectfully submits that the specification is enabling of the invention as claimed. The Examiner has not cited any deficiency in the disclosure as such, but has cited the data presented in the working examples as negating enablement, i.e., apparently as evidence of the type required by the court in *In re Marzocchi*, where the court held that:

> "it is incumbent on the Patent Office whenever a rejection [for enablement] is made, to explain *why* it doubts the truth or accuracy of any statement in the supporting disclosure and to back up such assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement."[2]

It is applicant's understanding that the Examiner is citing the data from the examples as meeting the burden imposed by *Marzocchi*.

Without conceding that the data cited by the Examiner does in fact satisfy the *Marzocchi* burden, applicant herewith submits a declaration of the inventor, Dr. Kathleen Campbell, which presents data that is submitted as establishing a significant effect of the administration of D-methionine in amelioration of noise-induced hearing loss. The data presented in the declaration were obtained in tests conducted by Dr.

[1] See Office action dated April 7, 2005 at page 2.
[2] In re Marzocchi, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971).

Campbell subsequent to the filing of the instant patent application. Based on these subsequent data, Dr. Campbell has shown that treatment with D-methionine after noise exposure (e.g., rescue dosing) significantly reduced the threshold shift measured at 21 days after the noise exposure. Accordingly, the enablement requirement of 35 U.S.C. § 112, first paragraph is satisfied for treating noise-Induced ototoxicity.

Additionally, reconsideration is respectfully requested of the rejection of claims 20-29, 32-41 and 57-71 under 35 U.S.C. § 112, second paragraph. As defined in claims 20 and 57, Applicant's invention is directed to a method for

> "preventing or treating ototoxicity in a patient exposed to noise for a time and at an intensity sufficient to result in ototoxicity."

As the specification states on page 34, noise, both impulse and chronic, is known, to cause ototoxicity. It inherently possesses this potential. Accordingly, with the information in the specification and knowledge in the art, a person of ordinary skill would know that exposure to noise for a sufficient time and at a sufficient intensity to result in ototoxicity is very likely to cause ototoxicity.

In any event, it is respectfully submitted that there is no indefiniteness in the language of claims 20 or 57. With regard to each of these claims, it can readily be determined whether a method as practiced is within the claim or outside of it. Accordingly, there is no necessity for the claim to expressly require that the ototoxicity be "caused by" the noise exposure. Consistent with practical clinical practice, where a subject is exposed to noise for a time and at an intensity sufficient to result in ototoxicity, the method comprises administration of methionine or a defined methionine-like compound as a prophylactic or ameliorative treatment for any ototoxicity that is indicated. The claims in question definitively so provide, and §112, second paragraph is fully satisfied.

Claim rejections under 35 U.S.C. § 103

It is respectfully noted that the Campbell reference (Hearing Research 102 (1996) 90-98) makes no mention of noise-induced ototoxicity; and that the reference contains not the remotest suggestion that D-methionine would have any value in dealing with a condition associated with noise. Nor is there any evidence that one skilled in the art would have any motivation to administer methionine to a patient exposed to noise for a time and at intensity sufficient to result in ototoxicity. In the absence of a motivation or suggestion in the art to modify the teachings of Campbell to treat a patient exposed to noise, a rejection for obviousness under §103 cannot properly be sustained.

In the absence of a motivation to modify the Campbell reference, the hypothetical eventuality posited in the Office action has no relevance to the patentability of the claim under §103. And as has already been established, the animals subjected to treatment as described in the Campbell reference were protected from noise. Accordingly, it is respectfully submitted the record fails to include evidence on which to base a rejection of the claims for either novelty or obviousness, and that the current rejection under §103 be withdrawn.

In view of the foregoing, it is respectfully submitted that all claims satisfy the requirements of 35 U.S.C. §112 and are patentable over the art under 35 U.S.C. §103.

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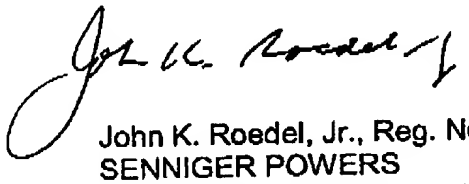
CONCLUSION

Favorable reconsideration and allowance of all pending claims are respectfully solicited.

Applicants do not believe that a fee is due in connection with this response. If, however, the Commissioner determines that a fee is due, he is authorized to charge Deposit Account No. 19-1345.

Respectfully submitted,



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